

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Timothy MURPHY

Application No.: 10/770,403

Filing Date: 4 February 2004

For: Methods for Treating Obesity

Art Unit: 3738

Examiner: Prebilic, Paul B.

Attorney Ref. No.: 010-001

Via EFS-Web

**RESPONSE UNDER 37 C.F.R. § 1.111**

**Mail Stop RCE**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In further response to the Office Action dated 22 August 2007 ("Office Action"), Applicant submits herewith additional evidence of non-obviousness of the pending claims. Favorable reconsideration, reexamination, and allowance of this patent application are respectfully requested in view of the entire record, including this newly submitted evidence, and the following remarks.

**Rejections**

Beginning at page 2, Claims 1, 3-6, 8-10, and 12-14 have been rejected under 35 U.S.C. § 103(a) as reciting subject matters that are allegedly obvious, and therefore allegedly unpatentable, over *Flesler* in view of *Ruiz*, for the reasons presented at pages 2-4. Beginning at page 4, Claim 11 has been rejected under 35 U.S.C. § 103(a) as reciting subject matter that is allegedly obvious, and therefore allegedly unpatentable, over *Flesler* and *Ruiz* and further in view of *Yurek*, for the reasons presented at page 4. Beginning at page 4 of the Office Action, Claims 23-25 have been rejected under 35 U.S.C. § 102(b) as reciting subject matters that are allegedly identically disclosed in *Flesler* or, in the alternative, under 35 U.S.C. § 103(a) as obvious over *Flesler* in view of *Ruiz*.

Applicant respectfully requests reconsideration of these rejections.

In the Office Action's "Response to Arguments" section, beginning at page 5, the Office Action states that the evidence Applicant previously submitted "is considered disconnected to the issue(s) of patentability". Applicant vigorously disagrees, because the evidence in fact goes directly to the heart of the inquiry under section 103(a).

The Office Action's derision of the qualifications of the NIH's panel of experts, appearing at the bottom of page 5, is plainly inappropriate. Because Mr. Prebilic has questioned their qualifications, however, Applicant has located (via public, internet searches) evidence of the level of skill of the members of the NIH panel. Applicant thus files concurrently herewith fifteen (15) biographies, curricula vitae (CV), or the like, one for each of the panelists. While Applicant will not belabor the record by going through each of them in detail, a brief review of each plainly demonstrates that each of the NIH panelists is certainly of at least ordinary skill in the art(s) to which this application's claims relate and, more likely, are of skill higher than that of the routineer in these arts. As Applicant has repeatedly asserted in this record, the opinion of the panelists, thrice documented in this record, is that a person of ordinary skill in the art would be strongly motivated not to perform the claimed methods, for the many reasons already articulated in this record.

The Office Action's logic is backwards concerning the relevance of the NIH's grant assessment to the patentability of the claimed methods. The Office Action draws fault with the fact that there is no evidence that the panel of experts evaluated the *Flesler* and *Ruiz* documents when making their evaluation of the safety and efficacy of Dr. Murphy's proposed methods; however, this concern is completely backwards, and entirely misses the point. The Office Action alleges that all of the claimed method steps are cumulatively disclosed in *Flesler* and *Ruiz*, the same method steps that are discussed at length in Dr. Murphy's grant proposals, and then alleges that the panel of experts did not evaluate what Mr. Prebilic says is in the prior art.

Therefore, assuming *arguendo* that Mr. Prebilic is correct (that *Flesler* and *Ruiz* together describe all of the steps in the claimed methods), it necessarily follows that the panel of experts would have been evaluating the combination of *Flesler* and *Ruiz*. Thus, according to Mr.

Prebilic's logic, the NIH panelists in fact were evaluating the hypothetical combination of *Flesler* and *Ruiz* when they gave their negative evaluations.

Furthermore, it is exactly because the panel of experts was not evaluating patentability that makes their assessment so powerful, and relevant. Again assuming *arguendo* that *Flesler* and *Ruiz* together describe all of the steps in the claimed methods, the same methods that are described in Dr. Murphy's grant requests, then it is abundantly clear that the panel of experts' opinion is that the hypothetical combination of *Flesler* and *Ruiz* is novel, risky, and even outrageous - that is, non-obvious. Mr. Prebilic makes the fundamental mistake of assuming that a person of ordinary skill in the art of medical methods would evaluate a new method for patentability, rather than what physicians actually evaluate them for: safety and efficacy. Thus, Mr. Prebilic's opinion is that a physician of ordinary skill in the art would purposefully jeopardize the health and welfare of a patient by combining the method steps of *Flesler* and *Ruiz* in order to arrive at Dr. Murphy's claimed combinations, and turns a blind eye to the untainted evidence that real experts in the field, not merely persons concerned with patentability such as Mr. Prebilic and the undersigned, find Dr. Murphy's proposed methods so novel and unusual that they believe the methods should not be practiced.

There are numerous other clear errors in the evaluation of the NIH documents:

(1) The Office Action questions the level of skill of the panel experts, because it is allegedly not clear which of them evaluated Dr. Murphy's proposal. Applicant thus has provided the evidence in the record to establish that they are at least of ordinary skill, and the inclusion of each one of them on the panel by the NIH plainly indicates that they are experts in the applicable field.

(2) The Office Action faults the evidence for not being in affidavit form; while true, the NIH documents are just as relevant as Mr. Prebilic's opinion, despite the fact that he also has not executed a Declaration to present his opinion as a U.S. government official, which is exactly what are each of the members of the panel of experts. Also, there are no grounds for those who volunteer to provide peer review for grant applications to be less than honest in giving their opinions. Furthermore, the Office Action underlying assumption makes no sense; the Office

Action assumes that, were the NIH panelists to make their evaluations in Declaration form, their opinions would somehow be transformed from 'novel, risky, and even outrageous' to the opposite, when evaluating Dr. Murphy's grant proposal for safety and efficacy.

(3) The Office Action's continued assertion, that the claim terms "permanently", "fixed", "invariable", and "continuously" are relative terms, is plainly preposterous. The Office Action points to no sources outside of this application which would support its position; the intrinsic evidence in this record, which has priority over any extrinsic evidence the Office Action could have included, plainly shows that Applicant's use of these terms in the claims excludes the interpretations the Office Action takes.

(4) The Office Action's assertion that the inclusion in *Flesler's* device of electronics that control the voltage applied to a patient's tissue means that *Flesler* can unequivocally control the patient's body's reaction to that voltage, is again completely groundless. Furthermore, the fact that *Flesler's* claims may have met the bare minimums of operability for patentable subject matter under 35 U.S.C. § 101, to wit, that they likely work a *de minimus* amount, does not mean that *Flesler's* methods and devices can actually control blood flow.

(5) Applicant faulted the prior Office Action's clear use of *impermissible* hindsight, that is, hindsight other than that that is intrinsic in the patentability inquiry; the Office Action presents no reasoning or additional facts in this record that weighs against this inescapable conclusion. *Flesler* and *Ruiz* are not "obviously" linked by someone of "ordinary" skill; indeed, there actually are not specialists who are experts in BOTH arts, a combination that would truly demonstrate extraordinary skill. Combining *Ruiz* and *Flesler* in the manner alleged in the Office Action to be obvious is artificial and only possible after reading this patent application. The fact that millions of medical articles have been published without any of them alluding to the claimed combination speaks to that simple fact. It also speaks to the novelty and non-obviousness of the claimed combinations, which is clear in that context. To propose that the claimed combination is obvious to someone of "ordinary" skill is preposterous, because it would require extraordinary skill, and because there actually is no one skilled in both of the applicable areas: placing vascular devices and electrical stimulation of smooth muscle.

Accordingly, the Office Action fails to make out a *prima facie* case of obviousness, including a rational reason related the claimed subject matter to make up for the deficiencies of the prior art with respect to the claimed combinations.

### **Conclusion**

Applicant respectfully submits that this application is in immediate and clear form for allowance. Accordingly, an early indication, via Notices of Allowance and Allowability, that all claims are allowed, is respectfully requested. Should any questions arise in connection with this application or should Mr. Prebilic believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application, the undersigned respectfully requests that he be contacted at the number indicated below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to our Deposit Account 50-2821.

Respectfully submitted,

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